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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.                       | CONFIRMATION NO.                   |
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| 09/776,874   | 02/06/2001  | Iris Pecker          | 01/21603                                  | 8407                               |
| <div>7590<br/>Martin D. Moynihan<br/>PRTSI, Inc.<br/>P. O. Box 16446<br/>Arlington, VA 22215</div> |             |                      | <div>EXAMINER<br/>HUTSON, RICHARD G</div> |                                    |
|  |             |                      | <div>ART UNIT<br/>1652</div>              | <div>PAPER NUMBER</div>            |
|  |             |                      | <div>MAIL DATE<br/>07/27/2007</div>       | <div>DELIVERY MODE<br/>PAPER</div> |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.



### **DETAILED ACTION**

Applicant's amendment of claim 127, and cancellation of claims 97-101 and 130-133, in the paper of 6/25/2007, is acknowledged and have been entered.

Claims 127-129 are at issue and are present for examination.

Applicants' arguments filed on 6/25/2007 have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

The entry of applicant's amendment has resulted in a withdrawal of the finality of the previous office action and the instant non-final rejection. Any inconvenience to applicants is regretted.

### ***Specification***

The disclosure is objected to because of the following informalities:

On page 93, line 19, applicants recite "sevsral" which should be "several".

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claim 128 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 128 is directed to all possible preparations comprising a heparanase protein wherein said heparanase protein merely comprises amino acid residues 500 to 543 of SEQ ID NO: 10 and is pure enough to elicit anti-heparanase antibodies, wherein said amino acid sequence has a phenylalanine residue at position 246. There is no disclosure of any particular structure to function/activity relationship in the single disclosed species. The specification also fails to describe additional representative species of these proteins by any identifying structural characteristics or properties other than the activities recited in claims 128, for which no predictability of structure is apparent. Given this lack of additional representative species as encompassed by the claims, Applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at [www.uspto.gov](http://www.uspto.gov).

Claim 128 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a protein or preparation comprising said protein

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having the amino acid sequence of SEQ ID NO: 10, said protein having heparanase activity or being so cleavable so as to acquire said heparanase activity, does not reasonably provide enablement for any protein or preparation merely comprising amino acid residues 500 to 543 of SEQ ID NO: 10. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The rejection was originally stated in the previous office actions as it applied to previous claims 97-99 and 130-133. In response to that rejection applicant's amended amendment of claim 127, and cancellation of claims 97-101 and 130-133. Regrettably claim 128 was mistakenly left out of the previous rejection when in fact it should have been included in the rejection for the reasons previously stated for claim 97 from which they depend.

Claim 128 is so broad as to encompass any preparations comprising a heparanase protein wherein said heparanase protein merely comprises amino acid residues 500 to 543 of SEQ ID NO: 10 and is pure enough to elicit anti-heparanase antibodies, wherein said amino acid sequence has a phenylalanine residue at position 246. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of proteins broadly encompassed by the claims. The claims rejected under this section of U.S.C. 112, first paragraph, place minimal structural limits on the claimed proteins. Since the amino acid sequence of a protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired

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activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the proteins' structure relates to its function. However, in this case the disclosure is limited to that preparations comprising a heparanase protein wherein said heparanase protein comprises the amino acid sequence of SEQ ID NO: 10 and is pure enough to elicit anti-heparanase antibodies, wherein said amino acid sequence has a phenylalanine residue at position 246.

As previously stated on the record, the specification does not support the broad scope of the claims which encompass the claimed preparations comprising a heparanase protein, because the specification does not establish: (A) regions of the protein structure which may be modified without effecting heparanase activity; (B) the general tolerance of heparanases to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any amino acid residue of a heparanase with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful. Because of this lack of guidance, the extended experimentation that would be required to determine which substitutions would be acceptable to retain the heparanase activity and the fact that the relationship between the sequence of a peptide and its tertiary structure (i.e. its activity) are not well understood and are not predictable, it would require undue experimentation for one skilled in the art to arrive at the majority of those methods of the claimed genus.

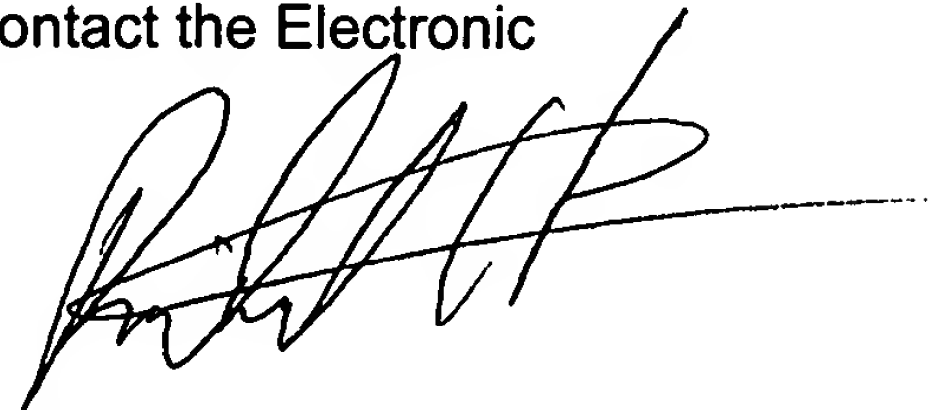
Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including any protein merely comprising amino acid residues 500 to 543 of SEQ ID NO: 10. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of those preparations having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G. Hutson whose telephone number is (571) 272-0930. The examiner can normally be reached on 7:30 am to 4:00 pm, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'R. Hutson', with a long horizontal line extending to the right.

Richard G Hutson, Ph.D.  
Primary Examiner  
Art Unit 1652

rg  
7/23/2007